



**INTEGRATIVE THERAPEUTICS INC.™**

NF Formulas PhytoPharmica  
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P 503.582.8386 F 503.582.0467

**ENZYMATIC THERAPY®**

**&  
PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 F 888 570.6460 (Enzymatic)  
P 920.469.9099 F: 920.469.4418 (Phyto)

**ENZYMATIC THERAPY**

*What Better feels like™*

2761 5 JUL 25 P2:18

June 23, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam.

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Petadolex® ASAP	Fast-acting Petadolex® ASAP contains a better butterbur extract to support healthy blood vessel tone in the brain, as well as normal blood flow in the brain.*	Purple Butterbur (Petasites hybridus) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster  
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 6/23/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Michael P. Devereux  
Chief Financial Officer

975 0162 LET 16446



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June 23, 2005

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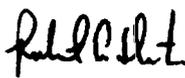
RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Petadolex® ASAP	Clinical studies have shown that Petadolex ASAP is safe, well tolerated and produces no significant adverse effects.*	Purple Butterbur (Petasites hybridus) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By 

Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 6/23/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

  
Michael P. Devereux  
Chief Financial Officer



# ENZYMATIC THERAPY

What *Better* feels like™

June 24, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Petadolex® ASAP	Effective for fast-acting, clear-headed comfort in both adults and children.*	Purple Butterbur (Petasites hybridus) Root Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

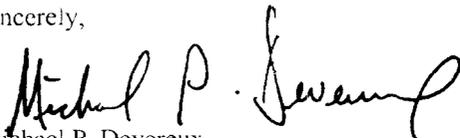
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date 6/24/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608

Sincerely,

  
Michael P. Devereux  
Chief Financial Officer

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